

111TH CONGRESS
2D SESSION

H. R. 5234

To amend the Public Health Service Act, the Employee Retirement Income Security Act, the Internal Revenue Code of 1986, and title XVIII of the Social Security Act to ensure transparency and proper operation of pharmacy benefit managers.

IN THE HOUSE OF REPRESENTATIVES

MAY 6, 2010

Mr. WEINER (for himself and Mr. MORAN of Kansas) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means and Education and Labor, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend the Public Health Service Act, the Employee Retirement Income Security Act, the Internal Revenue Code of 1986, and title XVIII of the Social Security Act to ensure transparency and proper operation of pharmacy benefit managers.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “PBM Audit Reform
5 and Transparency Act of 2010”.

1 **SEC. 2. PHARMACY BENEFITS MANAGER TRANSPARENCY**
2 **AND PROPER OPERATION REQUIREMENTS.**

3 (a) IN GENERAL.—

4 (1) AMENDMENTS TO THE PUBLIC HEALTH
5 SERVICE ACT RELATING TO THE GROUP MARKET.—

6 Subpart 2 of part A of title XXVII of the Public
7 Health Service Act (42 U.S.C. 300gg–4 et seq.) is
8 amended by adding at the end the following:

9 **“SEC. 2729. PHARMACY BENEFITS MANAGER TRANS-**
10 **PARENCY AND PROPER OPERATION RE-**
11 **QUIREMENTS.**

12 “(a) IN GENERAL.—Notwithstanding any other pro-
13 vision of law, a group health plan, and a health insurance
14 issuer providing health insurance coverage in connection
15 with a group health plan, shall not enter into a contract
16 with any pharmacy benefits manager to manage the pre-
17 scription drug coverage provided under such plan or insur-
18 ance coverage, or to control the costs of such prescription
19 drug coverage, unless the PBM satisfies the following re-
20 quirements:

21 “(1) REQUIRED DISCLOSURES TO GROUP
22 HEALTH PLAN OR HEALTH INSURANCE ISSUER IN
23 ANNUAL REPORT.—

24 “(A) IN GENERAL.—The PBM shall pro-
25 vide at least annually a report to each group

1 health plan and health insurance issuer with
2 which the PBM has a contract.

3 “(B) CONTENTS.—With respect to the
4 contract described under subparagraph (A), the
5 report under subparagraph (A) shall include—

6 “(i) information on the number and
7 total cost of prescriptions under the con-
8 tract filled at each of the following types of
9 pharmacies: mail order pharmacies, spe-
10 ciality pharmacies, and retail pharmacies;

11 “(ii) the aggregate average payments
12 under the contract, per prescription
13 (weighted by prescription volume), made to
14 such pharmacies;

15 “(iii) the average amount, per pre-
16 scription (weighted by prescription vol-
17 ume), that the PBM was paid by the plan
18 or issuer for prescriptions filled at such
19 pharmacies;

20 “(iv) the aggregate average payment
21 per prescription (weighted by prescription
22 volume) under the contract received from
23 pharmaceutical manufacturers, including
24 all rebates, discounts, price concessions, or
25 administrative and other payments from

1 pharmaceutical manufacturers, and a de-
2 scription of the types of payments, the
3 amount of these payments that were
4 shared with the plan, and the percentage
5 of prescriptions for which the PBM re-
6 ceived such payments;

7 “(v) information on the overall per-
8 centage of generic drugs dispensed under
9 the contract separately at retail and mail
10 order pharmacies, and the percentage of
11 cases in which a generic drug is dispensed
12 when available; and

13 “(vi) information on the percentage
14 and number of cases under the contract in
15 which individuals were switched, because of
16 the policies of the PBM, from the drug
17 originally prescribed to such individual by
18 the health care provider to a drug with a
19 higher cost to the plan or issuer, the ra-
20 tionale for these switches, and a descrip-
21 tion of the policies of the PBM applicable
22 to such switches.

23 “(2) PBM INTERACTIONS WITH PHARMACIES.—

24 “(A) OBLIGATIONS ON PBM.—A PBM
25 shall—

1 “(i) provide to pharmacies that con-
2 tract with the PBM—

3 “(I) the methodology and re-
4 sources that the PBM utilizes to de-
5 termine reimbursement (including to
6 calculate the maximum allowable cost
7 list); and

8 “(II) timely updates to pharmacy
9 product reimbursement benchmarks
10 used to calculate prescription reim-
11 bursement to pharmacies;

12 “(ii) not less than one time per week,
13 update the maximum allowable cost list
14 and the reimbursement benchmarks;

15 “(iii) establish a process for providing
16 prompt notification of the updates under
17 clause (ii) to the pharmacies; and

18 “(iv) pay pharmacies promptly for
19 clean claims, in a manner that is similar to
20 the manner in which claims are paid under
21 section 1860D–12(b)(4) of the Social Se-
22 curity Act (42 U.S.C. 1395w–112(b)(4)).

23 “(B) PBM LIMITATIONS.—A PBM may
24 not—

1 “(i) require that a pharmacy partici-
2 pate in one network of pharmacies man-
3 aged by such PBM as a condition for the
4 pharmacy to participate in another net-
5 work managed by such PBM;

6 “(ii) exclude an otherwise qualified
7 pharmacy from participation in a network
8 of pharmacies managed by such PBM if
9 the person or entity that owns the phar-
10 macy accepts the terms, conditions and re-
11 imbursement rates of the PBM’s contract;
12 and

13 “(iii) automatically—

14 “(I) enroll a pharmacy in a con-
15 tract with the PBM for participation
16 in a pharmacy network; or

17 “(II) modify an existing contract
18 regarding participation in a pharmacy
19 network,

20 without a written agreement of the person
21 or entity that owns the pharmacy.

22 “(C) CONTRACT REQUIRED.—The person
23 or entity that owns a pharmacy shall sign a
24 contract with a PBM before assuming responsi-

1 bility to participate in a network managed by a
2 PBM.

3 “(3) PBM OWNERSHIP INTERESTS AND CON-
4 FLICTS OF INTEREST.—With respect to an indi-
5 vidual who is a beneficiary of pharmacy benefits
6 managed by a PBM, the PBM may not mandate
7 that such individual use a specific pharmacy or enti-
8 ty to fill a prescription if—

9 “(A) the PBM has an ownership interest
10 in the pharmacy or entity; or

11 “(B) the pharmacy or entity has an owner-
12 ship interest in the PBM.

13 “(4) PHARMACY CHOICE.—With respect to an
14 individual who is a beneficiary of pharmacy benefits
15 managed by a PBM, such PBM may not provide in-
16 centives to such individual (including variations in
17 premiums, deductibles, co-payments, or co-insurance
18 rates) to encourage such individual to utilize a spe-
19 cific pharmacy or other entity to fill a prescription,
20 if such incentives only apply—

21 “(A) to a pharmacy or entity that the
22 PBM has an ownership interest in; or

23 “(B) to a pharmacy or entity that has an
24 ownership interest in the PBM.

1 “(5) PBM AUDIT OF PHARMACIES.—With re-
2 spect to an audit by a PBM (or an entity acting on
3 behalf of the PBM) of a pharmacy or other entity
4 (referred to in this paragraph as a ‘dispensing enti-
5 ty’) that contracts with a PBM to receive reimburse-
6 ment for dispensing prescription drugs to individuals
7 covered by benefits managed by such PBM, the
8 audit must comply with the following:

9 “(A) The PBM (or an entity acting on be-
10 half of the PBM) shall give the pharmacy or
11 other dispensing entity at least 15 days written
12 notice prior to commencing an audit.

13 “(B) The time period covered by the audit
14 may not exceed one year from the date the
15 claim being audited was submitted to or adju-
16 dicated by the PBM.

17 “(C) To the extent that the audit requires
18 the application of clinical or professional judg-
19 ment, such audit shall be conducted by or in
20 consultation with a pharmacist who is licensed
21 in the State in which the audit is being con-
22 ducted.

23 “(D) The PBM cannot require more strin-
24 gent record keeping by a pharmacy or dis-

1 dispensing entity than is required by State and
2 Federal law and regulation.

3 “(E) The PBM (or an entity acting on be-
4 half of the PBM) shall establish a written ap-
5 peals process that shall include procedures to
6 allow pharmacies and other dispensing entities
7 to appeal to the PBM the preliminary reports
8 and final reports resulting from the audit and
9 any resulting recoupment or penalty.

10 “(F) The PBM (or an entity acting on be-
11 half of the PBM) shall accept records of a hos-
12 pital, physician, or other authorized practitioner
13 that are made available to such PBM or entity
14 by the pharmacy or dispensing entity to vali-
15 date pharmacy records and prescriptions with
16 respect to confirming the validity of claims in
17 connection with prescriptions, refills, or changes
18 in prescriptions.

19 “(G) To the extent that an audit results in
20 the identification of any clerical or record-keep-
21 ing errors (such as typographical errors, scriv-
22 ener’s error, or computer error) in a required
23 document or record, the pharmacy or dis-
24 pensing entity shall not be subject to
25 recoupment of funds by the PBM unless—

1 “(i) the PBM can provide proof of in-
2 tent to commit fraud; or

3 “(ii) such error results in actual fi-
4 nancial harm to the PBM, a health insur-
5 ance plan managed by the PBM, or a con-
6 sumer.

7 “(H) The PBM (or an entity acting on be-
8 half of the PBM) shall not use extrapolation or
9 other statistical expansion techniques in calcu-
10 lating the amount of any recoupment or penalty
11 resulting from an audit of a pharmacy or dis-
12 pensing entity.

13 “(I) With respect to prescriptions covered
14 by a group health plan or health insurance
15 issuer, after the conclusion of any appeals
16 under subparagraph (E), a PBM shall—

17 “(i) disclose any recoupment of funds
18 from a pharmacy or dispensing entity
19 that—

20 “(I) results from an audit; and

21 “(II) is related to prescriptions
22 covered by such plan or issuer; and

23 “(ii) shall provide a copy of such dis-
24 closure to the pharmacy or dispensing enti-
25 ty.

1 “(6) PBM CONDUCT REGARDING COVERED IN-
2 DIVIDUALS.—

3 “(A) TREATMENT OF DATA.—

4 “(i) NOTICE OF SALE.—The PBM
5 shall notify a group health plan or health
6 insurance issuer, in writing, at least 30
7 days before selling, leasing, or renting any
8 utilization or claims data that the PBM
9 possesses as a result of a contract between
10 such PBM and plan or issuer, of—

11 “(I) the PBM’s intent to sell,
12 lease, or rent such data;

13 “(II) the name of the potential
14 buyer, lessor, or renter of such data;
15 and

16 “(III) the expected use of any
17 utilization or claims data by such
18 buyer, lessor, or renter.

19 “(ii) LIMITATIONS ON SALE.—The
20 PBM may not sell, lease, or rent utilization
21 or claims data that the PBM possesses as
22 a result of a contract between such PBM
23 and a group health plan or health insur-
24 ance issuer unless the PBM has received

1 written approval for such transaction from
2 the plan or issuer.

3 “(iii) OPT OUT FOR CONSUMERS.—

4 Before a PBM sells, leases, or rents utili-
5 zation or claims data that the PBM pos-
6 sesses as a result of a contract between
7 such PBM and a group health plan or
8 health insurance issuer, the PBM shall
9 provide each individual who is covered by
10 benefits managed by the PBM with an op-
11 portunity to affirmatively opt out of the
12 sale, leasing, or renting of data related to
13 such individual.

14 “(B) CONTACT WITH BENEFICIARIES.—A

15 PBM may not directly contact, by any means
16 (including via electronic delivery, telephonic,
17 SMS text or direct mail), an individual who is
18 covered by benefits managed by the PBM on
19 behalf of a group health plan or health insur-
20 ance issuer unless the PBM has the express
21 written permission of the group health plan or
22 health insurance issuer and the covered indi-
23 vidual (through a request by the plan sponsor)
24 to engage in such contact.

“(C) LIMITS ON SHARING DATA.—With respect to an individual covered by a benefit managed by a PBM, unless a patient has voluntarily elected to fill a prescription at a pharmacy, a PBM shall not transmit personally identifiable utilization or claims data related to such individual to such pharmacy if—

“(i) the PBM has an ownership interest in the pharmacy; or

“(ii) the pharmacy has an ownership interest in the PBM.

“(b) PHARMACY BENEFIT MANAGER; PBM DEFINED.—For purposes of this section, the terms ‘pharmacy benefit manager’ and ‘PBM’ mean an entity that provides pharmacy benefit management services on behalf of a group health plan or a health insurance issuer.”.

(2) AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT RELATING TO THE INDIVIDUAL MARKET.—

(A) IN GENERAL.—The subpart 2 of part B of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–51 et seq.) is amended by adding at the end the following:

1 **“SEC. 2754. PHARMACY BENEFITS MANAGER TRANS-**
 2 **PARENCY AND PROPER OPERATION RE-**
 3 **QUIREMENTS.**

4 “The provisions of section 2729 shall apply to health
 5 insurance coverage offered by a health insurance issuer
 6 in the individual market in the same manner as such pro-
 7 visions apply to a group health plan and a health insur-
 8 ance issuer providing health insurance coverage under that
 9 section.”.

10 (3) CONFORMING AMENDMENTS.—

11 (A) ERISA AMENDMENT.—

12 (i) IN GENERAL.—Subpart B of part
 13 7 of subtitle B of title I of the Employee
 14 Retirement Income Security Act of 1974
 15 (29 U.S.C. 1185 et seq.) is amended by
 16 adding at the end the following:

17 **“SEC. 715. PHARMACY BENEFITS MANAGER TRANS-**
 18 **PARENCY AND PROPER OPERATION RE-**
 19 **QUIREMENTS.**

20 “The provisions of section 2729 of the Public Health
 21 Service Act shall apply to a group health plan, and a
 22 health insurance issuer providing health insurance cov-
 23 erage in connection with a group health plan, in the same
 24 manner as such provisions apply to a group health plan
 25 and a health insurance issuer providing health insurance
 26 coverage under that section.”.

1 (ii) CLERICAL AMENDMENT.—The
 2 table of contents in section 1 of the Em-
 3 ployee Retirement Income Security Act of
 4 1974 is amended by inserting after the
 5 item relating to section 714 the following:

“Sec. 715. Pharmacy benefits manager transparency and proper operation re-
 quirements.”.

6 (B) IRC AMENDMENT.—

7 (i) IN GENERAL.—Subpart B of chap-
 8 ter 100 of the Internal Revenue Code of
 9 1986 (26 U.S.C. 9811 et seq.) is amended
 10 by adding at the end the following:

11 **“SEC. 9814. PHARMACY BENEFITS MANAGER TRANS-**
 12 **PARENCY AND PROPER OPERATION RE-**
 13 **QUIREMENTS.**

14 “The provisions of section 2729 of the Public Health
 15 Service Act shall apply to a group health plan, and a
 16 health insurance issuer providing health insurance cov-
 17 erage in connection with a group health plan, in the same
 18 manner as such provisions apply to a group health plan
 19 and a health insurance issuer providing health insurance
 20 coverage under that section.”.

21 (ii) CLERICAL AMENDMENT.—The
 22 table of sections for subpart B of chapter
 23 100 of the Internal Revenue Code of 1986
 24 is amended by inserting after the item re-

1 lating to section 9813 the following new
2 item:

“Sec. 9814. Pharmacy benefits manager transparency and proper operation requirements.”.

3 (b) PBMS AND MEDICARE PART D.—Subpart 2 of
4 part D of title XVIII of the Social Security Act is amended
5 by adding at the end the following new section:

6 **“SEC. 1860D-17. PHARMACY BENEFITS MANAGER TRANS-**
7 **PARENCY AND PROPER OPERATION RE-**
8 **QUIREMENTS.**

9 “The provisions of section 2729 of the Public Health
10 Service Act shall apply to health insurance coverage of-
11 fered by a prescription drug plan under this part in the
12 same manner as such provisions apply to a group health
13 plan and a health insurance issuer providing health insur-
14 ance coverage under that section.”.

15 (c) EFFECTIVE DATES.—

16 (1) GROUP MARKET AND MEDICARE.—The
17 amendments made by paragraphs (1) and (3) of
18 subsection (a) and by subsection (b) shall apply to
19 group health plan or health insurance issuers for
20 plan years beginning on or after the date of enact-
21 ment of this Act.

22 (2) INDIVIDUAL MARKET.—The amendment
23 made by subsection (a)(2) shall apply with respect to
24 health insurance coverage offered, sold, issued, re-

1 newed, in effect, or operated in the individual mar-
2 ket on or after the date of enactment of this Act.

○